

REMARKS

Claims 1-32 are cancelled herein without prejudice or disclaimer and claims 33-51 are new. Basis for the new claims is in the specification throughout and in claims as originally filed. For example, representative basis for claim 33 is in claim 1 and claim 20 as originally filed, in paragraphs 0049 and 0050 (e.g., last sentence of each paragraph) and in Figures 4, 7, 10 and 11. Accordingly, the new claims add no prohibited new matter.

The Office rejected claims 1, 2, 4, 5, 9-14, 22, 23 and 25-32 for alleged obviousness under 35 U.S.C. § 103(a) in view of Bieniasz and Mohler. Also, claims 1, 2, 4, 5, 9-14, 22, 23 and 25-32 were rejected for alleged obviousness under 35 U.S.C. § 103(a) in view of Moir and Mohler. The Office further rejected claims 1, 2, 4-6, 9-14 and 21-32 for alleged obviousness under 35 U.S.C. § 103(a) in view of Moir and Moosman.

Claimed matter is *prima facie* obvious only when a combination of cited documents (1) teaches or suggests all of the claimed elements, (2) the person of ordinary skill in the art was motivated to modify the document(s) as suggested in the Office action, and (3) there was a reasonable expectation of success. *See* MPEP 2142, *et seq.* Applicant respectfully asserts these rejections are inapplicable to the new claims because the combinations of cited documents (1) fail to teach or suggest elements of the claimed methods, (2) fail to provide a reasonable expectation of success or (3) teach away from the claimed methods. Applicant therefore does not traverse all rejections set forth in the Office action as traversal is not required to distinguish new claims 33-51 over the cited art. Applicant, however, does not necessarily accept or agree with rejections set forth in the outstanding Office action, and the new claims set forth herein are introduced to expedite prosecution.

The Combination of Bieniasz and Mohler Fails to Result in the Claimed Methods and Fails to Produce a Reasonable Expectation of Success

Applicant respectfully asserts the rejection of claims 1, 2, 4, 5, 9-14, 22, 23 and 25-32 for alleged obviousness under 35 U.S.C. § 103(a) in view of Bieniasz and Mohler is inapplicable to claims 33-51. Claim 33 is independent and the remaining claims 34-51 are directly or indirectly dependent. In claim 33 the first and second cells are different and specific cell types. In particular, the first cell is a HeLa cell and the second cell is a 293T cell, or the first

cell is a 293T cell and the second cell is a HeLa cell. Bieniasz fails to teach or suggest a method for detecting fusion between different cell types as only fusion of the same type of cell is described (e.g., fusion between 293T cells or fusion between COS cells). Mohler is directed to fusion between cells of the same type, murine myoblasts (C2F3cells). Mohler also discusses detection of cell fusion by lacZ complementation when two of the same type of cells are fused (murine myoblasts). Mohler does not cure the defects of Bieniasz as it does not address fusion between different cell types, and in particular, the claimed combinations of cells. Accordingly, the combination of Bieniasz and Mohler fails to teach or suggest all of the elements of claim 33 and its dependent claims.

Further, one of ordinary skill in the art would not have any reasonable expectation of successfully practicing the claimed methods based on the cited documents. There would have been no reasonable expectation of success that the first reporter molecule fragment and the second reporter molecule fragment would combine, produce a functional reporter molecule, and produce a signal. The claimed methods encompass fusion of different cell types such that contents of the fused cell is a heterogeneous mixture based on contribution from two different cell types. Bieniasz does not disclose alpha complementation and Mohler only discloses fusion and lacZ complementation in cells of the same type. Such fusion of the same type of cells produces a homogeneous intracellular environment. The resultant intracellular environment produced by the fusion of two different cell types would not have been reasonably expected to result in a functional complementation assay due to the unknown effects of the combination of various molecules brought together from the different types of cells.

Thus, the claimed methods would not have been obvious to a person of ordinary skill in the art as the combination of Bieniasz and Mohler fails to teach or suggest all of the claim elements and does not provide a reasonable expectation of success.

Moir in Combination with Mohler or Moosman Fails to Result in the Claimed Methods and Moir Teaches Away from the Claimed Methods

Applicant respectfully asserts the rejections of (1) claims 1, 2, 4, 5, 9-14, 22, 23 and 25-32 under 35 U.S.C. §103(a) in view of Moir and Mohler, and (2) claims 1, 2, 4-6, 9-14 and 21-32 under 35 U.S.C. §103(a) in view of Moir and Moosman, are inapplicable to claims 33-51. Claim 33 is independent and the remaining claims 34-51 are directly or indirectly dependent. As

discussed above, the fused cells in claim 33 are of different cell types -- the first cell is a HeLa cell and the second cell is a 293T cell, or the first cell is a 293T cell and the second cell is a HeLa cell.

Moir does not address fusion of cell types specified in claim 33 (i.e., 293T and HeLa). Moir discloses cell fusion assays in which at least one of the cell lines is a T-cell line. Mohler, as previously discussed, discloses fusion between the same cell type, murine myoblasts (C2F3 cells). Moosman does not disclose cell fusion, but discloses alpha complementation of LacZ in HeLa cells. Thus, the combination of cited documents fails to teach or suggest all of the claim elements.

Furthermore, Moir states T-cells should be utilized in cell fusion assays as they are the primary targets of HIV (page 811 last paragraph):

From the premise that human T lymphoid cells are the primary targets of HIV, we reasoned that such cells would best mimic the *in vivo* situation. Here we report on the use of a CD4-negative T cell line for expressing HIV-1 envelope glycoproteins while diminishing possible intracellular trapping of Env by CD4.

Based on this teaching of Moir, a person of ordinary skill in the art would not have been motivated to carry out a fusion assay without at least one of the cell fusion partners being a T-cell, as this approach would be departing from the *in vivo* situation. Moir therefore teaches away from the claimed fusion assays, where both of the cells to be fused are not T-cells.

Accordingly, the claimed methods would not have been obvious to a person of ordinary skill in the art because (1) Moir in combination with Mohler or Moosman fails to teach or suggest all of the elements of claims 33-51, and (2) Moir is not properly combined with Mohler or Moosman since it teaches away from the claimed methods.

CONCLUSIONS

The claimed methods involve fusion of different and specific types of cells in an assay in which fusion is brought about by a viral envelope protein or receptor presented on the surface of the specific cells and detection of fusion is by alpha complementation in the fusion product. The combinations of cited documents (1) fail to teach or suggest elements of the claimed methods, (2) fail to provide a reasonable expectation of success, and/or (3) teach away from the claimed methods. Accordingly, it is respectfully requested the Office withdraw the rejections under 35 U.S.C. §103(a).

Applicant therefore respectfully asserts claims 33-51 are in condition for allowance. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at (858) 623-9470 so they may be promptly resolved.

In the unlikely event a pertinent document is separated from this submission and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account 503473**.

Respectfully submitted,

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